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| EXAMINER |
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FUBARA, BLESSING M

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| ART UNIT | PAPER NUMBER |
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1618

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11/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|----------------------------------------|--|
| Office Action Summary | Application No. 09/995,358 | Applicant(s) ZECCHINO ET AL. | |
| | Examiner BLESSING M. FUBARA | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-16 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-16 and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The examiner acknowledges receipt of Appeal Brief filed 8/01/08 and 8/19/08. Claims 1-10, 12-16 and 18-21 are pending.

1. In view of the Appeal Brief filed on 8/01/08, PROSECUTION IS HEREBY REOPENED. New Grounds of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3-5, 6-10, 12-15 and 18-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description.

5. Claims 1, 12 and 19 use polymeric acid gellant. The specification as filed describes ammonium poly(acryldimethyltauramide-co-vinylformamide) as polymeric sulfonic acid gellant without describing other polymeric sulfonic acids that are gelling agents. Appellant does not have possession for all polymeric sulfonic acid gellant and poly(acryldimethyltauramide-co-vinylformamide) does not

6. Claims 1-10, 12-16 and 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 12 and 19 require the composition to contain "less than about 1 percent surfactant." The less than about contains two limitations, one limitation that is less than 1 percent and another limitation that contains about 1 percent and in less than 1 percent, the percent surfactant cannot be at 1.1, which meets the about 1% limitation.

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The examiner suggests amending the claims to recite either less than 1 percent or about 1 percent.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-3, 6-10, 12-15 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wheeler (WO 97/32559) in view of Clariant product brochure or in view of Beerse et al. (US 6,294,186).

Wheeler teaches the preparation of bi-liquid foam by combining oil-based bi-liquid foam and an aqueous gel, gelling polymer and the pH is adjusted to less than or equal to 7 with citric acid (page 6, lines 1-10 and 20-23 and examples 1-4) with the composition meeting claims 3, 13.

Wheeler teaches cosmetic or pharmaceutical composition comprising a stable dispersion that comprises oil-based bi-liquid foam and an aqueous gel (abstract) with the bi-liquid foam

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meeting the biliquid foam of the claims. The oil-based bi-liquid foam of Wheeler is from 1% to 80% by weight of the total formulation (lines 1-4 of 4th full paragraph of page 3) meeting claims 9, 10, 14, 15. The composition Of Wheeler also comprises silicone oils wherein the oils can be cyclomethicone, dimethicone, dimethicone copolyol, lanolin and dimethiconol (5th full paragraph of page 3) meeting claim 8. The composition of Wheeler uses low levels of surfactant (second full paragraph of page 3) and Wheeler teaches a formulation further comprising from 0.05% to 0.5% of surfactant and active ingredient in the aqueous or oily phase (lines 4-7 of 4th full paragraph of page 3) with this amount meeting the requirements for the surfactant amounts in claims 1, 12 and 19. Wheeler teaches that the low level of surfactant incorporated into the formulation comprises quaternary ammonium sulfonium salts, amphoteric surfactant, anionic surfactant, alpha-olefin sulfonate, and ester-linked sulfonate (3rd full paragraph of page 4). Wheeler exemplifies compositions that are adjusted to pH 5.5 (example 2), pH 6.5 (examples 1, 3) and pH 7 (example 4) which suggests that pH of the solutions to be at less than or equal to 7 such that it would have been obvious to prepare the compositions at pH of less than or equal to 7 meeting the requirements of claims 1, 12 and 19. The aqueous phase contains polymer or gum such as alginate gums or their salts, guar gum, locust bean gum, xanthan gum, gum acacia, gelatin, hydroxymethylcellulose or its sodium salt, hydroxyethyl- cellulose, hydroxypropylcellulose, carboxymethylcellulose, bentonites, magnesium aluminum silicates, "Carbomers" (salts of cross-linked polymers of acrylic acid), or glyceryl polymethacrylates or their dispersions in glycols, or any appropriate mixture of any of these polymers and gums in an amount between 0.05-20% (page 4, first full paragraph), all of which are gelling agents having the ability to gel compositions and with points within the disclosed amount touching points

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within the recited amount of 0.01 to 10% and thus meets requirement for amount of gellant in claims 1, 6, 12, 18, 19 and 21. The aqueous phase also contains salt (first full paragraph of page 5) meeting the requirement for the presence of salt in claims 1, 12 and 19. Wheeler is silent on the amount of salt to be used, regarding the percent amounts of salt, it would be obvious to use appropriate amount of salt that would be provide desired pearlescence and luster to the gelled composition.

However, Wheeler does not use polymeric sulfonic acid as a gelling agent. However, Clariant product brochure teaches Aristoflex AVC or copolymer of polyacryldimethyltauramide and vinylformamide gelling agent for aqueous systems and thickening agent for oil-in-water emulsions. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the bi-liquid foam by gelling the composition with alginate gums or their salts, guar gum, locust bean gum, xanthan gum, gum acacia, gelatin, hydroxymethylcellulose or its sodium salt, hydroxyethyl cellulose, hydroxypropylcellulose, carboxymethylcellulose, bentonites or magnesium aluminum silicates according to the teachings of Wheeler. One having ordinary skill in the art would have been motivated to substitute alginate gums or their salts, guar gum, locust bean gum, xanthan gum, gum acacia, gelatin, hydroxymethylcellulose or its sodium salt, hydroxyethyl cellulose, hydroxypropylcellulose, carboxymethylcellulose, bentonites or magnesium aluminum silicates gelling agent with another gelling agent such as polyacryldimethyltauramide-co-vinylformamide (Aristoflex) with the expectation that the aqueous composition will be gelled.

It is also known in the art that xanthan gum and ARISTOFLEX AVC are thickening agents (see column 38, lines 25-32 of US 6,294,186). Xanthan gum is one of the gelling/thickening

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agents of Wheeler (page 4, first full paragraph). Since xanthan gum and ARISTOFLEX AVC have been recognized in the art to be thickening agents, one thickening agent can be use in place of the other to obtain the same gelling of thickening effect. Therefore, taking the teachings of Wheeler and Beerse, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success to substitute one thickening agent for another, in this case ARISTOFLEX AVC can be substituted for xanthan gum.

Response to Arguments

10. Appellant's arguments filed 8/01/08 have been fully considered but they are not persuasive.

In response to Appellant's argument that Wheeler (WO 97/32559) does not suggest Appellant's invention including the use of the polymeric sulfonic acid gellant or the surprising unexpected advantages of using the polymeric sulfonic acid gellant in a bi-liquid foam because the Wheeler reference does not disclose or suggest composition that comprises an oil containing bi-liquid foam dispersed in a salt-containing aqueous phase, and with the aqueous phase comprising a polymeric sulfonic acid gellant and having a pH of less than 7, the salt in the aqueous gel is at from about 1 to about 10 percent, the gellant is at from about 0.01 to about 10 percent and the surfactant is present at less than about 1% of the composition, the examiner notes the following. a) the cosmetic or pharmaceutical composition of Wheeler comprises dispersion of an oil based bi-liquid foam and an aqueous gel (abstract; page 3) with the oil in the bi-liquid foam being silicon oil (fifth paragraph of page 3); b) the aqueous phase contains polymer or gum such as alginate gums or their salts, guar gum, locust bean gum, xanthan gum, gum acacia, gelatin, hydroxymethylcellulose or its sodium salt, hydroxyethyl- cellulose,

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hydroxypropylcellulose, carboxymethylcellulose, bentonites, magnesium aluminum silicates, "Carbomers" (salts of cross-linked polymers of acrylic acid), or glyceryl polymethacrylates or their dispersions in glycols, or any appropriate mixture of any of these polymers and gums in an amount between 0.05-20% (page 4, first full paragraph), all of which are gelling agents having the ability to gel compositions and with points within the disclosed amount touching points within the recited amount of 0.01 to 10%; c) the aqueous phase also contains low levels of surfactant in an amount of 0.05 to 0.5% (lines 4 and 5 of fourth full paragraph of page 3) with the disclosed %amount of the surfactant meeting the limitation of less than 1% recited in the claims; d) the aqueous phase also contains salt (first full paragraph of page 5). Since Wheeler exemplifies compositions that are adjusted to pH 5.5 (example 2), pH 6.5 (examples 1, 3) and pH 7 (example 4), which suggests that pH of the solutions to be at less than or equal to 7 such that it would have been obvious to prepare the compositions at pH of less than or equal to 7 meeting the requirements of claims 1, 12 and 19. It is thus noted that Wheeler teaches the claimed composition according to claim 1 and method of thickening a composition according to claim 19. The examiner agrees with the Appellant that Wheeler does not teach the use of polymeric sulfonic acid as a gelling agent and that is the reason the Wheeler reference does not anticipate the claimed invention. But Wheeler uses other polymers and gums that are recognized thickening or gelling agents and one gelling agent can be used in place of another to achieve expected gellation/thickening.

In response to Appellant's arguments that the Clariant brochure does not teach or suggest Appellant's invention, it is noted that the Clariant reference describes commercially available gellant product, ammonium poly(acryldimethyltauramide-co-vinylformamide), also known as

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AVC, for gelling or thickening aqueous systems at low pHs; the Clariant product brochure was therefore relied upon for teaching that AVC is suitable gelling/thickening agent for aqueous systems; the Clariant product brochure was not relied upon for teaching bi-liquid foam dispersed in salt containing aqueous phase that comprises polymeric sulfonic acid gellant and having pH of less than 7.

Therefore, taking the teachings of the prior art, one having ordinary skill in the art at the time the invention was made would have had reasonable expectation of success that substituting the gellant AVC for either of the thickening/gelling agents of Wheeler would provide the anticipated gelling/thickening of an aqueous phase that contains salt and surfactant.

In response to appellant's argument that Wheeler in view of the Clairiant brochure failed to render obvious the claimed invention because the ordinary skilled artisan would not have predicted that polymeric sulfonic acid gellant could be used to stably gel the aqueous phase of a bi-liquid containing gel composition, it is noted that because the AVC gellant of the Clariant brochure is used to gel or thicken aqueous system, it would have been reasonable to expect that it the AVC could be used in place of the other thickening agents in Wheeler to gel/thicken the aqueous phase.

In response to Appellant's contention that carboxyvinyl polymers such as Carbopols used as gellant in the Wheeler WO '559 reference have poor tolerance for salts such that compositions containing salts would have poor stability citing US 6,197,318 at column 11, line 65 to column 14 line 17, it is noted that the Wheeler WO '559 reference discloses the use of polymers and gums in addition to Carbopol according to page 4, first full paragraph, where the aqueous phase is said to contain polymer or gum such as alginate gums or their salts, guar gum, locust bean

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gum, xanthan gum, gum acacia, gelatin, hydroxymethylcellulose or its sodium salt, hydroxyethyl- cellulose, hydroxypropylcellulose, carboxymethylcellulose, bentonites, magnesium aluminum silicates, "Carbomers" (salts of cross-linked polymers of acrylic acid), or glyceryl polymethacrylates or their dispersions in glycols, or any appropriate mixture of any of these polymers and gums in an amount between 0.05-20%. The reference, US 6,197,318 cited by Appellant to demonstrate that Carbopols have poor tolerance for salts does not show poor salt tolerance for gelling agents such as alginate gums or their salts, guar gum, locust bean gum, xanthan gum, gum acacia, gelatin, hydroxymethylcellulose or its sodium salt, hydroxyethyl- cellulose, hydroxypropylcellulose, carboxymethylcellulose, bentonites, and magnesium aluminum silicates. Further, while Appellant points to the intolerance of Carbopol for salts, there is evidence in the art that AVC and xanthan gums and mixtures can be used as thickeners for compositions (column 38, lines 25-27, 30 and 31 of US 6,294,186) noting that xanthan gum is one of the thickeners/gellants of the Wheeler WO'559 reference.

In response to Appellant's further assertion that Wheeler WO'559 fails to teach polymeric sulfonic acid and salt in Example 1, which composition contains less than 1% surfactants and having a pH of 6.5 and that the surfactant levels of Examples 2 and 3 are higher than the required less than 1%, it is noted that a reference is not limited to its working examples. It is further noted Wheeler WO'559 discloses the aqueous phase to contain gelling agents such as alginate gums or their salts, guar gum, locust bean gum, xanthan gum, gum acacia, gelatin, hydroxymethylcellulose or its sodium salt, hydroxyethyl- cellulose, hydroxypropylcellulose, carboxymethylcellulose, bentonites, and magnesium aluminum silicates (first full paragraph of page 4) and salts (lines 8-11 of the first full paragraph of page 5); the gellant is at 0.05 to 20%

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(line 2 of 1st paragraph of page 4); the surfactant is at 0.05-0.5% (lines 4 and 5 of 4th paragraph of page 3) which is less than 1%. It is further noted that, in determining obviousness, a combination of references need not result precisely in applicant's structure, rather, the question is whether the invention would have been obvious in light of the combination. See *In re Thornberg*, 103 F.2d 387 (CCPA 1939). In this case, Wheeler in view of the Clariant gelling agent renders the claims obvious.

In response to Appellants argument that Wheeler does not teach less than 1% surfactant, it is noted that Wheeler in lines 4 and 5 of page 3 teaches less than 1% surfactant.

In response to Appellant's statement that Wheeler does not teach polymeric sulfonic acid, the examiner agrees with the Appellant and that is why the rejection is made under 35 USC 103(c) and the examiner notes that Wheeler teaches other gellants and one gellant can be used in place of the other to achieve gelling of the composition.

In response to Appellant's argument that the Clariant reference does not contemplate difficulty of gelling at low pH composition containing significant amount of salt, it is noted that the Clariant reference specifically states gelling at low pH and the Clariant reference is relied upon for teaching the use of AVC as a gelling agent at low pH's and not for teaching presence of salt. Regarding the amount of salt and the presence of salt in the Wheeler reference, it is noted that claim 1, 12 and 19, for example recites the broad term salt and the disclosure of salt in Wheeler meets that limitation. Upon further review and consideration, claims 4, 5 and 16 reciting salts of alpha- or beta-hydroxy acids have not been included in the rejections above.

In response to Appellant's arguments that page 3, line 26 to page 4, line 6 that the gellants in Wheeler '559 performs in non-acidic formulations and are incapable of creating stable

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dispersions in the presence of low levels of electrolytes, it is noted that Wheeler '559 strongly suggest acidic pHs by adjusting the compositions in examples 1-6 to pHs of less than 7 of 7. In response to Appellant's mention of the filed 11/01/2003, it is noted that the declaration was addressed on pages 2 and 3 of the office action of 1/30/2004.

11. Claims 1-10, 12-16 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wheeler (WO 97/32559) in view of Beerse et al. (US 6,294,186) and further in view of Vatter et al. (US 6,224,888) or France et al (US 4,184,978).

12. Wheeler in view of Beerse has been shown above to render obvious claims 1-3, 6-10, 12-15 and 18-21. The composition of Wheeler is a cosmetic that can be delivered to the skin and hair (2nd, 3rd and 4th full paragraphs of page 5) to cleansing and conditioning. However, the composition of Wheeler in view of Beerse does not contain the salts recited in claims 4, 5 and 16. But these salts of alpha- or beta- hydroxy acids are known in the art to be used in cosmetic compositions.

13. For example, sodium lactate and salts of lactic acid or alpha hydroxy acids are known moisturizers for skin care (see column 12, lines 35, 62-67 of US 6,224,888). Therefore, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that adding the moisturizers such of the salts of lactic acid would effectively aid in moisturizing and conditioning of the skin and hair. It is also known in the art that lactic acid and its salts are found naturally in the skin environment to maintain proper pH and moisturizing levels and known to be included in cosmetics (see column 5, lines 45-48). Therefore, one having ordinary skill in the art at the time the invention was made would have

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reasonable expectation of success that adding the moisturizers such of the salts of lactic acid would effectively aid in moisturizing and maintaining the normal pH of the skin and hair.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618